

b.) Remarks

Claims 43, 72 and 81 have been amended in order to correct their punctuation only. Accordingly, no new matter has been added.

Claims 42, 43, 46, 53, 63, 72, 73, 80, 81, 84, 91 and 99-102 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement and as failing to be supported by an enabling specification.

This is the sole remaining rejection, all claims having otherwise been indicated as free of the prior art.

As to the rejection, the Examiner states

It appears that the present specification does not provide support for the limitation 'a coating film which enhances release in intestine or sustained release, and is destroyed when a molding material comprising said granule is compressed at tableting pressure greater than 1.3 ton/cm².' In the Remarks filed 10/24/06, applicant pointed out page 14, lines 5-9 and experiments 3-4 for support of the limitation 'coating film is destroyed when a molding material comprising said granule is compressed at tableting pressure greater than 1.3 ton/cm²', however, upon reconsideration, it appears that the experiments do not support the above limitation. Specifically, Experiments 3 and 4 as pointed out by the applicant show that tablet compressed at pressure of 1000 kg/punch (less than 1.3 ton) lost sustained release function and enteric function respectively". (Emphasis added.)

This above is not well-understood since Applicants explained in detail for the Examiner's convenience at page 9-10 of their May 18, 2009 Amendment that Experiments 3 and 4 (operated at 500 kg/punch) is the same as 1.3 ton/cm². That is to say, respectfully submitted, the Examiner has not addressed Applicants' analyses. For that

reason, the Office Action has confused both the claim terminology (e.g., ton/punch is not the same as ton/cm²) and the showings of Experiments 3-6 and comparisons 4-8.

This subject matter is, accordingly, again clarified below for the record.

By way of background, as disclosed in page 6, lines 8-19 in the original specification, Applicants found both the film coated on the surface of the granule and the function of the granule were damaged (page 6, lines 10-19) when tableted at 1-2 ton/cm² (page 6, lines 8-9).

0.7 ton/cm²

The tablets having practical hardness can be produced when being tableted at or above the tableting pressure of 0.7 ton/cm². This is clearly seen from the result in experiment 1 which shows a preferable result (hardness and disintegration time of tablet) when the tableting pressure is “0.7 ton/cm²”, see page 50, line 1 to page 51, line 5 and table 2.

1.3 ton/cm²

Each of the experiments and comparisons shown in tables 3 and 4 use the rotary type tableting machine “A” shown in the embodiment of invention 1 (see page 60, lines 11-15 and page 62, lines 10-17). The diameter of the punch and die of the rotary type tableting machine “A” is 7 mm, as discussed from page 46, line 23 to page 47, line 1.

As explained in the May 18, 2009 Amendment, the unit of “kg/punch” converts to the unit “ton/cm²” as follows:

Punch diameter = 7mm. Therefore, punch radius = 3.5 mm and accordingly, $500 \text{ kg/punch} = 0.5 \text{ ton} \div \{\pi \times (.7 \text{ cm}/2) \times (.7 \text{ cm}/2)\} = 1.3 \text{ ton/cm}^2$.

The specification shows these tablets, produced at the tableting pressure of “500 kg/punch” (e.g., 1.3 ton/cm^2) in experiments 3 and 4 provide excellent results (see page 65, line 11 to page 68, line 4 and table 3 and table 4 in the original specification).

Additionally, experiment 5 and 6 of table 4 further illustrate the result of dissolution test of the tablet produced at the tableting pressure of “500 kg/punch” (e.g., 1.3 ton/cm^2). Very preferable results are obtained since the coating film on the surface of granules, which enhances release in intestine or sustained release, is not damaged during tableting.

In view of the above remarks, Applicants submit that all of the Examiner's concerns are overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 42, 43, 46, 53, 63, 72, 73, 80, 81, 84, 91 and 99-102 remain presented for continued prosecution.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

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